K030690

APR 3 0 2003

CODONICS
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510(k) Summary **807.92(c)**

1 Submitter Information: **807.92(a)(1)**

1.1 **Submitter:**

Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.2 **Manufacturing Facility:**

Same as above

1.3 **Representative:**

Not applicable at this time

1.4 **Contact:**

Roderick Dayton, Phone:(440) 243-1198 / Fax : (440) 243-1334
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.5 **Date:** February 28, 2003

2 Device Name **807.92(a)(2) & 807.92(a)(3)**

2.1 **Camera, Multiformat, Radiological**

2.2 **Classification Name:** **Medical Image Hardcopy Devices**

Classification Number: 892.2040

2.3 **Classification Code:** LMC

2.4 **Trade/Proprietary Name:** EP-1000 Medical Color Dry Imagers

2.5 **Predicate Devices:** Codonics NP-1600 Series Medical Printers (Premarket notification K962364) and Seiko ColorPoint 1720 (Premarket notification K991282).

3 Device Description **807.92(a)(4)**

3.1 **Function**

The EP-1000 Imagers are dry, thermal, color printer/imagers. The devices produce continuous tone, diagnostic quality B/W and color images on reflective, incident light viewed media. The images produced via dye-diffusion technology are photographic and medical color matched quality.

3.2 **Scientific Concepts:**

Digital images are input directly to industry standard parallel (IEEE 1284) or Universal Serial Bus (USB 1.1) interfaces. The EP-1000 recognizes only its own proprietary image format which employs a 24-bit, RGB encoding for each pixel to be printed. Lossy data compression is not employed. Software drivers can be written or adapted for a plurality of host imaging applications and operating systems, which can translate image data of any format to the EP-1000 format.

The EP-1000 does not process or alter the received image data in any way. Host imaging applications or drivers can be designed to pre-compensate image data with gamma, contrast, rotation, scaling, etc; but the EP-1000 can only print the image data as received.

Imaging is accomplished via directly-modulated discrete-element thin-layer linear thermal print head technology. The recording medium is heat activated dye-diffusion of color onto photographic quality ChromaVista® paper. The action of heat on the dye-diffusion media produces a precision mixing of colors, which diffuse the medium top layer. The image formation is accomplished without wet chemistry processing common to many laser film imaging systems in use today.

3.3 **Physical And Performance Characteristics:**

In the case of medical image hard copy devices, important performance characteristics, which affect the effectiveness and safety, relate to the fidelity of the modulation transfer function. Spatial frequency response, color resolution, density response and full image field uniformity combine to affect the final image. Characteristic response of thermal print head and film response must be mapped and compensated for to achieve suitable performance.

Pixel size (81μ for the EP-1000 Imagers) produces a pixel resolution of 12.4 pixels/mm or 314 dpi. The color palate produces 256 levels of 16.7 millions colors. The SMPTE resolution and contrast pattern and uniform density response function confirms quality suitable for the intended medical imaging use.

4 Device Intended Use: **807.92(a)(5)**

4.1 The intended uses of the EP-1000 Imagers is high resolution hard copy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes however is not limited to, nuclear medicine, ultrasound, CT (especially 3-D reconstruction), MRI, and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.

5 Device Technological Characteristics: 807.92(a)(6)

5.1 The characteristics of the EP-1000 Imagers compare substantially to the Codonics NP-1600 Series Medical Printers (Premarket notification K962364), the Codonics Horizon® Ci Medical Imager (Premarket notification K021054) with respect to color, reflective media printing, and Seiko ColorPoint 1720 (Premarket notification K991282) in system function and intended uses. The technology and applications are substantially equivalent to models of printers already cleared to market by the FDA. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category.

6 Testing and Equivalence: 807.92(b)(1), 807.92(b)(2) & 807.92(b)(3)

6.1 In the code implementation, electrical compliance tests, simulation, printer resolution pattern testing, and clinical studies, results and outcomes have been thoroughly reviewed with proper operation and intended functions verified. The device passed a series of electrical safety tests including UL-1950 and CAN/CSA-C22.2 No 950-95. The devices comply with electromagnetic standards of FCC Part-15, Subpart-B, Class-A. Laboratory tests have documented expected results consistent with predicate devices currently in commercial distribution, particularly with regard to the predicate NP-1600.

Codonics believes the EP-1000 Imagers to be substantially equivalent to Medical Image Hardcopy Devices currently in commercial distribution in the U.S. We have selected the Codonics NP-1600 Series Medical Printers (Premarket notification K962364) and the Seiko ColorPoint 1720 (Premarket notification K991282) as the predicate devices for our claim of substantial equivalence, Attachment 6 contains information describing these predicate devices and provides a comparison of the EP-1000 Imagers to the predicate device(s) and describes how any differences of note are substantially equivalent.

7 Hazard Analysis and Safety Concerns

7.1Hazard analysis on this product has been performed throughout the product concept and testing phases of the product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes and their effects
- Development of methodologies to control the occurrence of hazards and to constrain their effects;
- Determine any effect on patient safety and system effectiveness

The potential hazards associated with this product are not different than those of other hardcopy image components. These are primarily related to the failure of computer system components, and may be variously obviated by decisions taken by the end users of the product. None of the failures are expected to materially contribute to patient death or injury.

It is our conclusion that no hardware or software component, operating in a properly configured environment, whose latent design defect would be expected to result in death or injury of the patient. Thus the "level of Concern" is "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

Mr. Rick Dayton
Director of Quality
Codonics, Inc.
17991 Englewood Drive
MIDDLEBURG HEIGHTS OH 44130

Re: K030690
Trade/Device Name: EP-1000 Medical Color Dry Imager
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: March 4, 2003
Received: March 5, 2003

Dear Mr. Dayton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K03 0690

Device Name: EP-1000 Medical Color Dry Imagers

Models: EP-1000

Indications For Use:

The intended uses of the EP-1000 Imagers is high resolution hard copy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes however is not limited to, nuclear medicine, ultrasound, CT (especially 3-D reconstruction), MRI, and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.

The intended uses are identical to the Codonics NP-1600 Series Medical Printers (Premarket notification K962364) as a color, reflective media imager. The intended uses are identical to the Seiko ColorPoint 1720 (Premarket notification K991282) in terms of color, reflective media output.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lejnma

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030690